

K073173

510(k) SUMMARY

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 600
York, PA 17405-0801

CONTACT: Helen Lewis

DATE PREPARED: November 8, 2007

JAN 23 2008

TRADE OR PROPRIETARY NAME: Self-adhesive Cement

CLASSIFICATION NAME: Dental cement, 21 CFR 872.3275

PREDICATE DEVICES: Unicem, K020256 and MaxCem, K041474

DEVICE DESCRIPTION: Self-adhesive Resin Cement consists of a base paste and a catalyst paste, mixed to form a dual-curing cement. The Cement is available in five shades and is delivered in double-barrel syringes and unit dose systems.

INTENDED USE:

Self-adhesive Resin Cement is intended for the cementation of indirect restoratives including ceramic, composite and metal-based inlays, onlays, crowns, bridges, and posts.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in Self-adhesive Resin Cement have been used in legally marketed devices and/or were found safe for dental use. Self-adhesive Resin Cement has been evaluated and passed biocompatibility testing for cytotoxicity, genotoxicity, irritation and sensitization.

We believe that the prior use of the components of Self-adhesive Resin Cement in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of Self-adhesive Resin Cement for the indicated uses.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K073173
Trade/Device Name: Self-Adhesive Resin Cement
Regulation Number: 21 CFR 872.3275 (b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: November 8, 2007
Received: November 13, 2007

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K073173

Device Name: Self-adhesive Resin Cement

Indications for Use:

Self-adhesive Resin Cement is intended for the cementation of indirect restoratives including ceramic, composite and metal-based inlays, onlays, crowns, bridges, and posts.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rums
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073173

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